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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,201	01/27/2004	Yoji Tanijiri	019941-002010US	3314

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,201	TANIJIRI ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-6 are being presented for examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/31/2005 ~~was filed~~ is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Ishibashi et al. (EP 1 125 576 A1), in view of Mizumoto et al. (EP 0 745 382 A1).

Claims are drawn to enteric sustained release fine particles of tamsulosin or its salt that can be contained in tablets that disintegrate in the buccal cavity and a method of producing the enteric sustained release fine particles.

Ishibashi teaches a process for producing spherical fine particles containing a drug that is an easily swallowed, controlled release preparation (Abstract). The fine particles are coated with "enteric coating and slow-release coating" (page 6, lines 3-7). Regarding the coating of the fine particles, Ishibashi teaches coating with "a water-

insoluble and water impermeable acrylic resin polymer, ... coating with a multilayer film, ... coating with a mixture of enteric coating agent and water-insoluble coating agent, ... (page 6, lines 17-28). Ishibashi also teaches "examples of easily swallowed, controlled release preparations" (page 6, lines 31-46) and that the "coated drug-containing spherical microparticles can also be used in the production of conventionally used preparations such as ... tablets" (page 6, lines 47-48). The mean particle size is 200μm, and the preferable particle size is 60-150μm (page 5, lines 49-50). Dissolution tests (according to the Japanese Pharmacopeia) were performed on the coated fine particles at pH 6.8 to test the enteric coating release (page 8, lines 32-36).

Ishibashi does not teach fine particle preparations containing tamsulosin.

Mizumoto teaches intrabuccally dissolving compressed moldings that show quick disintegration and dissolution in the buccal cavity (Abstract). Mizumoto teaches "drugs for use in patients having difficulty in swallowing tablets, ... and for use in patients whose water drinking is limited" (page 6, lines 4-7). The α-adrenergic receptor blocker tamsulosin hydrochloride is given as an example and as a preferable active ingredient (page 7, line 3 and line 35).

A person having ordinary skill in the art at the time the invention was made would have found it obvious to combine the coated spherical fine particle teaching of Ishibashi with the drug tamsulosin hydrochloride taught by Mizumoto. The motivation for this combination is provided by the teaching in Mizumoto that drug preparations which rapidly disintegrate in the buccal cavity can be advantageously used by patients with difficulty swallowing tablets and by patients whose water drinking is limited. The α-

adrenergic receptor blocker tamsulosin hydrochloride is used for patients with dysuria caused by prostatomegaly. These patients generally limit their water intake to prevent frequent urination. Therefore, the rapidly disintegrating tablets containing the fine enterically coated drug particles would provide the ideal delivery platform.

Regarding the dissolution tests disclosed in claims 1 and 6, Ishibashi teaches testing the dissolution of the preparation. Since the fine particles have been enterically coated, a person with ordinary skill in the art would find it obvious to test a tablet containing the enterically coated particles first at a low pH (1.2) to ensure a low dissolution rate in the gastric milieu and then at a higher pH (6.8) to ensure the release of the drug in the intestinal milieu. A person with ordinary skill in the art would use the protocols of testing outlined in the pharmacopoeia (in the instant case the Japanese Pharmacopoeia was used). Accordingly, a person with ordinary skill in the art would modify the formulation of the tablet and the enterically coated fine particles in order to achieve the desired dissolution profile for the particular drug (in this case tamsulosin hydrochloride) during routine optimization.

Regarding claims 2, 3 since Ishibashi teaches enteric and slow release coatings, it would be obvious to a person skilled in the art to use "enterosoluble" and "water-insoluble" substances.

Regarding claim 4, since Ishibashi teaches coating with multilayer films for controlled release, it would be obvious to a person skilled in the art to use a "controlling film and/or matrix" to modify the release rate of tamsulosin hydrochloride.

Regarding claim 5, it would be obvious to a person skilled in the art to have the enteric coating as the outermost layer and the water insoluble layer as the inner layer. This is because the enteric coating has to protect the fine particles from gastric acid degradation and allow the dissolution in the intestines.

Therefore, given the teachings of Ishibashi and Mizumoto, a person having ordinary skill in the art would find it obvious to produce enteric sustained release fine particles of tamsulosin for tablets that disintegrate in the buccal cavity and have an optimal dissolution profile.

Conclusion

1. No claims are allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600